S/N 10/772964 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Claudia MATTERN

Examiner:

unknown

Serial No.:

10/772964

Group Art Unit:

1646

Filed:

February 4, 2004

Docket No.:

08788.0024US01

Title:

CONTROLLED RELEASE DELIVERY SYSTEM FOR NASAL

APPLICATIONS

CERTIFICATE UNDER 37 CFR 1.8:

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents, Mail Stop Patent Application, P.O. Box 1450, Alexandria, VA 22313-1450 on June 4, 2004.

Name: Sarah Monfeldt

INFORMATION DISCLOSURE STATEMENT (37 C.F.R. § 1.97(b))

Mail Stop Patent Application Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner.

This statement should be considered because it is submitted before the mailing date of a first Office Action on-the-merits. Accordingly, no fee is due for consideration of the items listed on the enclosed Form 1449.

In accordance with 37 C.F.R. §1.98(a)(2), a copy of each document or other information listed on the enclosed Form 1449 is provided.

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that the reference(s) are not "prior art." Moreover, Applicants do not represent that a reference has been thoroughly reviewed or that any relevance of any portion of a reference is intended.

Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Form 1449, marked

as being considered and initialed by the Examiner, to the undersigned with the next official communication.

Please charge any additional fees or credit any overpayment to Deposit Account No. 13-2725.

23552
PATENT TRADEMARK OFFICE

Dated: June 4, 2004

JJG:smm

Respectfully submitted,

MERCHANT & GOULD P.C. P.O. Box 2903 Minneapolis, Minnesota 55402-0903 (612) 332-5300

John J. Gresens

Reg. No. 33,112

FORM 14492 ENFORMATION DISCLOSURE STATEMENT	Docket Number: 08788.0024US01	Application Number: 10/772964			
in an application	Applicant: Claudia MATTERN				
IN AN APPLICATION (i) e several sheets if necessary)	Filing Date: February 4, 2004	Group Art Unit: n/a			
EXTENT . TO ADEME					

			U	I.S. PATENT DOCUMEN	NTS				
EXAMINER INITIAL	DOCUMENT NO.		T NO. DATE NAME CLA	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE			
			FOR	EIGN PATENT DOCUM	 IENTS		·		
	DOCUMENT NO.		DATE COUNTRY	CLASS	SUBCLASS	TRANSLATION			
						YES	NO		
	WO 98//47535		Oct. 1998	wo	-				
	GB 2 237 510		May 1991	UK			:		
		OTHER	DOCUMENTS	S (Including Author, Title,	Date, Pertinent I	Pages, Etc.)		l	
J		Journal of	Pharmaceutics	"Bioadhesive and formulat , 127 (1996) 115-133.					
		Hussain, Anwar A., et al., "Testosterone 17 β-N, N-Dimethylglycinate Hydrochloride: A Prodrug with a Potentia for Nasal Delivery of Testosterone", <i>Journal of Pharmaceutical Sciences</i> , Vol. 91, No. 3, March 2002, pp. 785-789.							
		Ko, Kuang-Ta, et al., "Emulsion formulations of testosterone for nasal administration", <i>J. Microencapsulatio</i> 1998, vol. 15, no. 2, pp. 197-205.							
		Cicinelli, Ettore, et al., "Progesterone administration by nasal spray", Fertility and Sterility, vol. 56, no. 1, July 1991, pp. 139-141.							
		Cicinelli, E., et al., "Nasally-administered progesterone: comparison of ointment and spray formulations", Elsevier Scientific Publishers Ireland Ltd., 13 (1991), pp. 313-317.							
		Cicinelli, E., et al., "Progesterone administration by nasal spray in menopausal women: comparison between two different spray formulations", Gynecol. Endocrinol., 6(1992), pp. 247-251.							
		Cicinelli, Ettore, et al., "Nasal spray administration of unmodified progesterone: evaluation of progesterone serum levels with three different radioimmunoassay techniques", Maturitas Journal of the Climacteric & Postmenopause, 19(1994), pp. 43-52.							
			nn, F., et al., "B o. 727-729.	ioavaiability of nasally adn	ninistered proges	sterone", Fertility a	nd Sterility, v	ol. 46, no.	
				delivery progesterone power 132, n. 10 (1993), pp. 402		comparison with c	oral administra	ation", Bol	

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EXAMINER DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.

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Examiner:

unknown

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Docket:

08788.0024US01

Confirmation

5308

Notice of Allow.

n/a

No.:

Date:

CONTROLLED RELEASE DELIVERY SYSTEM FOR NASAL APPLICATIONS

Due Date:

n/a

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Alexandria, VA 22313-1450 on June 4, 2004.

Mail Stop Patent Application Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

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Sir:

We are transmitting herewith the attached:

☐ Transmittal Sheet in duplicate containing Certificate of Mailing

☐ Information Disclosure Statement, Form 1449, 11 Reference(s)

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Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers or any future reply, if appropriate. Please charge any additional fees or credit overpayment to Deposit Account No. 13-2725. A duplicate of this sheet is enclosed.

MERCHANT & GOULD P.C. P.O. Box 2903, Minneapolis, MN 55402-0903 612.332.5300

J. Gresens:smm